

REMARKS

Claims 1-22 are pending. No new matter has been added by way of the present amendment. For instance, claims 9 and 10 have been amended to remove the recitation of certain diseases. Also, other claims have been amended to recite the nature of the patient treated or subject to prevention. Accordingly, no new matter has been added.

In view of the following remarks Applicant respectfully requests that the Examiner withdraw all rejections and allow the currently pending claims.

Issues Under 35 U.S.C. §102(b)

The Examiner has rejected claims 1-5, 7, 10, 11, 13, 16, 17, 19 and 22 under 35 U.S.C. §102(b) as being anticipated by Fuhrman, *The American Journal of Clinical Nutrition*, Vol. 66, Pages 267-275 (1997) (hereinafter referred to as Fuhrman). Applicant respectfully traverses this rejection.

Applicant respectfully submits that Fuhrman fails to suggest or disclose the currently claimed subject matter. The rejected claims are drawn to methods for lowering a risk factor in a patient, lowering at least two risk factors simultaneously or preventing a patient from suffering from a particular condition.

The risk factors are selected from blood pressure, blood glucose concentration, LDL susceptibility to retention, LDL susceptibility to aggregation, blood total cholesterol and LDL levels, and blood triglycerides and VLDL concentration. The conditions are selected from hypertension, chronic renal failure, hypercholesterolemia, and hypertriglyceridemia.

The present methods involve administering an effective amount of a licorice extract which is water-insoluble and free from glycyrrhizinic acid to the patient. However, Fuhrman fails to suggest or disclose this specific subject matter. Fuhrman discloses that the oxidation susceptibility of LDL reduces upon intake of a licorice extract. Applicant stresses that Furman discloses none of the risk factors or conditions currently claimed, either explicitly or implicitly, as being affected by licorice intake.

The Examiner has stated, "it is not a theory that oxidative damage by free radicals causes disease". This is true. Nevertheless, it is a theory that an antioxidant that is effective in lowering LDL susceptibility to oxidation is inherently effective in lowering blood pressure, blood glucose concentration, LDL susceptibility to retention, LDL susceptibility to aggregation, blood total cholesterol, LDL levels, blood triglycerides, or VLDL concentration.

Applicant respectfully disagrees with the Examiner's rationale that the lowering of a patient's risk to disease such those recited in the claims is inherent to the disclosure of Fuhrman. That is, Applicant asserts that the Examiner's rationale is based upon an unproven hypothesis and insufficient for the establishment of a theory of either inherency or obviousness. Furthermore, Applicant has presented two articles that show that an antioxidant that is effective in lowering one risk factor or treating one disease is ineffective towards another risk factor or disease condition. These articles, therefore, rebut the theory of inherency suggested by the Examiner.

A theory of inherency, such as that raised by the Examiner in the first 5 lines and last 11 lines of page 4 of the Office Action, must be supported by facts and/or technical reasoning that reasonably support a determination that the allegedly inherent characteristic necessarily flows from the teachings of the prior art. *Ex parte Levy* 17 USPQ2d 1461 (BPAI 1990) (emphasis added). In order for prior art to anticipate a claimed compound on the ground it is inherently produced in a prior art process, the inherency must be certain. *Glaxo, Inc. v. Novopharm Ltd.*, (EDNC 1993) 830 F. Supp 871, 29 USPQ2d 1126; *Ex parte Cyba* (POBA 1966) 155 USPQ 756; *Ex parte McQueen* (POBA 1958) 123 USPQ 37. The fact that a prior art article may inherently have the characteristics

of the claimed product is not sufficient. *Ex parte Skinner* (BPAI 1986) 2 USPQ2d 1788. Inherency must be a necessary result and not merely a possible result. *In re Oelrich* (CCPA 1981) 666 F2d 578, 212 USPQ 323; *Ex parte Keith et al.* (POBA 1966) 154 USPQ 320.

The Examiner's statement that the prior art proves that "antioxidants lower risk factors" (page 4 of the Office Action, last three lines) is not applicable to the present claims. Applicant is not attempting to claim the lowering of a risk factor by an anti-oxidant in general, but rather lowering the specific risk factors that are listed in the claims by a licorice extract that is water insoluble and free of glycyrrhizinic acid.

Accordingly, in the present instance, the evidence does not support an assertion that the cited art inherently achieves the current claim limitations. If the Examiner wishes to maintain this assertion, Applicant requests that the Examiner provide documentary evidence. In this regard the Examiner is requested to refer to 37 C.F.R. §1.104(c)(2) and *In re Zurko*, 59 U.S.P.Q. 2d 1693, 1697 (Fed. Cir. 2001). Alternatively, if the Examiner is relying upon personal knowledge to support the finding of what is known in the art, the Examiner is respectfully requested to provide an affidavit or declaration setting forth specific factual statements and explanation to support such a finding. In this regard the Examiner is referred to 37 C.F.R. §1.104(d)(2).

In summary, Applicant respectfully submits that a valid *prima facie* case of anticipation has not been presented. Reconsideration and withdrawal of this rejection is respectfully requested.

Issues Under 35 U.S.C. §103(a)

The Examiner has rejected claims 6, 8, 12, 14, 18 and 20 under 35 U.S.C. §103(a) as being obvious over Fuhrman. Applicant respectfully traverses.

The Examiner asserts that it would have been obvious to one of ordinary skill in the art at the time of the claimed invention being made to select the licorice extract of Fuhrman and provide for treatment methods of inflammation or to provide for lowering triglycerides and LDL levels without decreasing HDL levels. Applicant disagrees.

The Examiner again relies on the theory that the licorice extract eliminates free radical oxidation, and therefore obviously is useful for treating inflammation, high triglycerides, and high LDL. Applicant again takes issue with the Examiner's hypothesis, as if being an anti-oxidant as such or being effective in reducing the oxidation susceptibility of LDL, renders obvious the effectiveness of Fuhrman's extract towards the recited conditions and risk factors. In particular, LDL

susceptibility to retention and to aggregation has no direct relationship with LDL susceptibility to oxidation. Hypertension is known to be unaffected by many anti-oxidants. Also, total cholesterol includes both oxidized and non-oxidized cholesterol, and therefore, the susceptibility of LDL to oxidation is not directly connected to the LDL levels.

The Examiner's position, as if every anti-oxidant is expected to be effective against every oxidative damage, is not a valid one, as well known in the art, and as demonstrated by the articles presented by Applicant in response to the previous Office Action.

In responding to the argument filed by Applicant on November 24, 2004, the Examiner has drawn Applicant's attention to various disclosures in Fuhrman; nevertheless, none of these disclosures contain a description that renders obvious the invention currently claimed.

The Examiner states (on page 6 of the Office Action) that Fuhrman "clearly does teach the administering of an amount of a licorice extract which is demonstrated to be effective by Fuhrman for reduction of susceptibility of LDL to oxidation of which has been implicated in cardiovascular disease. Hypertension has also been implicated in cardiovascular disease. Also the prior art has recognized glycyrrhizinic acid to be causative of hypertension.

Further, Fuhrman et al teach a glycyrrhizinic acid free licorice extract, therefore, to treat hypertension would have been *prima facie* obvious." Applicant respectfully disagrees.

The fact that hypertension and cardiovascular diseases exist many times together does not lead to the expectation that Fuhrman's licorice extract will be effective against hypertension. Stress and anxiety also go together with cardiovascular disease, and it is far from being obvious that Fuhrman's licorice extract is effective against stress and anxiety.

While the prior art may be interpreted to suggest that an extract with glycyrrhizinic acid is not a good candidate for treating hypertension, the prior art does not suggest that Fuhrman's extract is effective against hypertension. Being free of glycyrrhizinic acid is not disclosed in the prior art to be sufficient or beneficial for treating high blood pressure.

Based upon these distinctions above, the Examiner has failed to present a valid *prima facie* case of obviousness.

Even absent the above distinctions, Applicant submits that Fuhrman teaches away from the present invention. For instance, Fuhrman reports that the consumption of licorice extract by humans has not been found to have any significant influence on plasma cholesterol, LDL concentration, or any other medical

characteristics examined (see the paragraph bridging the left and right column of page 268 of Fuhrman). Thus, this teaches away from the claimed invention. The Examiner's suggested explanation that Fuhrman's failure to show decrease in LDL level is because "this study was conducted on young healthy humans so the rate of lipid peroxidation was most likely normal which may explain why no changes were observed" may explain, hypothetically in hindsight, the differences between the results reported by Fuhrman and those disclosed in the present application. Still, a skilled person would be discouraged to use Fuhrman's extract to treat conditions that Fuhrman found not to be affected by the extract. Thus, Fuhrman teaches away from the present invention.

Further, regarding anti-inflammatory influence of a licorice, Fuhrman discloses (at page 268, lines 14-18) that it is attributed in the art to glycyrrhizinic acid, of which the extract recited in the present claims is free. Thus, Fuhrman again teaches away from the presently claimed invention.

At most the Examiner's rejection amounts to an "obvious to try" standard, which is improper in the presentation of a *prima facie* case of obviousness. "Obvious to try" is not a valid test of patentability. In re Mercier, 185 USPQ 774 (CCPA 1975); see also Hybritech Inc. v. Monoclonal Antibodies, 231 USPQ 81 (Fed. Cir. 1986). Accordingly, Applicant respectfully submits that the

Examiner has failed to present a valid *prima facie* case of obviousness. Reconsideration and withdrawal of this rejection is respectfully requested.

The Examiner has also rejected claims 9, 15 and 21 under 35 U.S.C. §103(a) as being obvious over Fuhrman in view of "admitted prior art (see specification at page 1, lines 10-12)." Applicant respectfully traverses this rejection.

As indicated above, the prior art of Fuhrman, even in view of what the Examiner has designated as "admitted" prior art, fails to suggest or disclose a method for treating a patient suffering from a condition listed in claim 9, namely, hypertension, chronic renal failure, hypercholesterolemia, and hypertriglyceridemia.

Accordingly, Applicant respectfully submits that there exists no *prima facie* case of obviousness. Reconsideration and withdrawal this rejection is respectfully requested.

In view of the above, Applicant respectfully submits that neither a case of anticipation nor a case of or *prima facie* obviousness was presented. Accordingly, the Examiner is respectfully requested to withdraw all rejections and allow the currently pending claims.

If the Examiner has any questions or comments, please contact Craig A. McRobbie, Registration No. 42,874 at the offices of Birch, Stewart, Kolasch & Birch, LLP.


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If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. § 1.16 or under § 1.17; particularly, extension of time fees.

Respectfully submitted,

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